



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/727,151

12/02/2003

David K. Swanson

03-0515 (US01)

5305

23410

7590

12/28/2009

Vista IP Law Group LLP
2040 MAIN STREET, 9TH FLOOR
IRVINE, CA 92614

EXAMINER

ROANE, AARON F

ART UNIT

PAPER NUMBER

3769

MAIL DATE

DELIVERY MODE

12/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/727,151	Applicant(s) SWANSON, DAVID K.	
	Examiner Aaron Roane	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14, 17, 19, 20, 32-37, 40, 42 and 44-51 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14, 17, 19, 20, 32-37, 40, 42 and 44-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 14, 17, 19, 20, 32-34, 36, 37, 40-42 and 45-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 32-34 recite “stimulation element too small to form a transmural myocardial lesion” which is indefinite as it is the combination of the size, configuration and energy delivery that determine whether the transmural myocardial lesion is formed and not merely the size. Therefore this will be interpreted as a functional limitation in order to provide an examination.

Invocation of 112, sixth paragraph

Claim 32 recites in lines 6-9 “means, associated with the tissue stimulation element, for securing the surgical apparatus to the tissue structure by engaging a single side of the tissue structure and pressing the stimulation element against the single side of the tissue structure,” which is interpreted by the examiner as Applicant invoking 112, sixth paragraph. The examiner equates the means for securing as equivalent to the anchor of claim 33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 14, 17, 32-34, 36, 37, 40-42 and 45-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess (U.S. Patent 4,144,890) in view of Edwards et al. (U.S. Patent 5,398,683).

Regarding claims 14, 17, 32-34, 36, 37, 40-42 and 45-51, Hess discloses a device comprising: a tissue stimulation element, in the form of a stimulation **electrode (“small flat disk electrode”, see col. 3:36-52 and figure 7)** configured to emit stimulation energy that is applied to tissue, wherein a size of the tissue stimulation element is too small to form a transmural myocardial lesion; and an anchor or means for securing (collectively portions defined by 25, 27, 31, 33 and 37 in col. 2:42-55 and figures 1-3 or portions defined by 41-44 in col. 3:9-18 and figures 4-6), associated with the tissue stimulation element, the anchor being configured to secure the surgical apparatus to the tissue by piercing the tissue and pressing the stimulation element against the tissue, see col. 2:12- col. 3:52 in general. **Hess further disclose “[o]ne type of electrode which may be used is formed by allowing half turns of the helically-coiled conductor to**

Art Unit: 3769

project through the bottom face of the insulating base as illustrated at 53 in FIG. 7.

In some cases, a small flat disk electrode resting against the tissue to be stimulated may also be entirely sufficient,” see col. 3:36-52 and figure 7. Hess is silent as to the diameter of the “small flat disk electrode.” Hess also fails to disclose a second tissue stimulation element. Edwards et al. disclose a medical catheter device and teach providing the catheter with “two pacing electrodes 75 are 0.035” platinum dot electrodes, and are positioned substantially diametrically opposite each other” (0.035” is 0.889 mm) in order to provide pacing/stimulating electrical energy to tissue, see col. 8:21-25 and figure 8. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Hess, as taught by Edwards et al., to use two small disk like electrode of about 0.889 mm in size that are positioned diametrically opposite each other on the device in order to provide pacing/stimulating electrical energy to tissue.

Regarding claims 19 and 20, Hess discloses that the anchor comprises a flexible carrier (elongated element defined by ends 42 and 42) that is non-linear when in the relaxed state, as it has a u-shaped or cup shaped transverse cross-section, see col. 3:9-18 and figures 4-7.

Response to Arguments

Applicant's arguments with respect to claims 14, 17, 32-34, 36, 37, 40-42 and 45-51 have been considered but are moot in view of the new ground(s) of rejection. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action.

As a courtesy to Applicant and in the hopes of expediting prosecution, the examiner would like to make a few comments.

First, the only 112 rejection that remains is on all the claims and the recited "stimulation element too small to form a transmural myocardial lesion." As pointed out earlier, it is the combination of the size, configuration and various energy delivery parameters comprising total energy deposited, power density, elapsed time and the like that determine whether the transmural myocardial lesion is formed and not merely the size. Additionally, it should be noted that the power supply or generator determine the various energy delivery parameters, and no such supply/generator has been positively recited. Although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims. See *In re Self*, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982). See *In re Prater*, 415 F.2d 1393, 162 USPQ 541 (CCPA 1969) and *In re Winkhaus*, 527 F.2d 637, 188 USPQ 129 (CCPA 1975). If Applicant wishes to claim a particular size and shape for the stimulation element, Applicant should explicitly do. It should be noted that Applicant has positively recited a size range and at least a shape in the broad sense that the stimulation element do not and/or can not pierce tissue,

Art Unit: 3769

but the recited. However, the recited “stimulation element too small to form a transmural myocardial lesion” remains indefinite.

Secondly, Applicant should note that Hess clearly discloses a stimulation element/electrode that does not pierce tissue as noted in the column and lines of the Hess patent cited in the above rejections.

The Applicant is invited to request an interview to discuss suggestions to find an acceptable conclusion of the prosecution for all parties.

This action is made FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

Art Unit: 3769

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 8:30AM-7PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Aaron Roane/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit
3769